Title	Assessing Quality of Tissue Specimens
SOP Code	SOP120_02
Effective Date	04-Jan-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines minimum assessment and testing of morphological features that should be in place to evaluate the quality of tissue samples stored in the biorepository; This SOP does not describe an assessment of molecular quality or detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

This procedure describes minimum steps that should be followed to ensure that tissue samples collected, stored, and distributed, are of sufficient morphological caliber to meet the research needs of the investigators.

3.0 RESPONSIBILITIES

This procedure applies to all biorepository personnel that are responsible for assessing the quality of tissue specimens.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Documentation of Frozen Tissue Specimens

Note: Biorepositories may establish and use criteria to determine the particular research application for which tissue may be utilized. This system does not assess quality, but serves as a prediction that certain molecular elements may be conserved. The choice of setting the Test Levels of specimens is left to the discretion of the biorepository.

5.1.1 Record level of specimen quality, based on harvesting times recorded during specimen collection, harvesting, and freezing.

5.1.2 In the event of any deviation from normal procedure, the quality of samples may be compromised. In this case, assess any adverse change in quality and adjust the quality level assigned to reflect this.

5.1.3 Record adjustments to the assigned quality level.

5.2 Quality Assessment - Pathology Review

5.2.1 Reviews of tissue should be done by a qualified pathologist.

5.2.2 Develop a defined scoring system that allows a ‘quality score' to be assigned to a tissue or molecular sample that has undergone assessment at a designated quality control laboratory. The score (assigned levels) will help in the interpretation of the quality assessment results and correlate to the suitability of the tested specimen for specified research applications.

5.2.3 Basic quality control practice must include a morphologic review of the following:

- Formalin fixed tissue
- Snap frozen tissue
- Fresh tissue
- FFPE
- H&E stained slide for each relevant FFPE block

5.2.4 The review should confirm and assess, as applicable to specimen type:

- Tissue type and assessment of diagnosis
- Tumour type and grade
- Presence of tumour cells
- Percent cellularity of tumour and stroma
- Percent necrosis or signs of degradation
- Presence of inflammatory cells

5.2.5 Upon microscopic examination of the slide, store a digital image of an area representative of the tissue sample in the repository database.

5.2.6 Record results of review in database.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD. http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research, 3rd Edition, 2012, http://www.isber.org

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP120_01	01-Aug-2012	Original version
SOP 120_02	04-Jan-2016	5.2.1 stipulated qualified pathologist. 5.2.2 -5.2.6 sequence renumbering Updated references. Removed OTRN logo.